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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,833	12/12/2001	Calvin A. Saravis	TDT-2	7194
1473	7590	02/26/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

015,833

Applicant(s)

SARAVIS

Examiner

CAUNORJ

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/23/03.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-53 is/are pending in the application.
Of the above claim(s) 40-53 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-39 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The claims pending are 1-53.

Applicant's election without traverse of Group I (claims 1-34) in Paper filed 10/23/03 is acknowledged.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 37 recitation of a "naturally-chelating nonimmunogenic polymer" is unclear as to what is meant by "naturally." A first interpretation can be simply that this is any nonimmunogenic polymer, from any source, that by its nature (i.e. as an intrinsic property) has the capability of chelating a metal ion. The fact that "naturally chelating" is expressed as a hyphenated word is consistent with this interpretation. A second interpretation can be that the non-immunogenic polymer is from or is derived from a natural source (e.g. alginates from algae).

In claim 9; it is not clear which of the Markush group members of base claim 7 is being further described. The base claim refers to "aluminum salts." However "aluminum magnesium hydroxide" of claim 9 is not an "aluminum salt" because a "salt" is properly defined as a product formed by reaction of an acid and base.

The term "cold-water fish" in claim 32 is a relative term which renders the claim indefinite. The term "cold-water fish" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant's

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disclosure sets forth no temperature limit according to which one may determine if the fish is found in "cold-water" or in "warm-water".)

In claim 38 "is depotized" is unclear. Is applicant claiming the composition after it has been injected and become "depotized" in an animal? Is applicant referring to a property of the composition? If the latter, then applicant may recite – becomes depotized upon immunization – in lieu of "is depotized."

In claim 39 "dynamically bound by a plurality of chelators" is unclear. Does this mean that the metal ion exchanges between several different chelating moieties within the nonimmunogenic polymer? Does it mean that there are one or more chelators, other than those of non-immunogenic polymer, present (e.g. as in claims 21-22)?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 10-12, 34-35 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowersock et al (5,674,495).

Bowersock et al (495) teach immunogenic compositions comprising alginate particles containing antigen. The alginate component is cross-linked by a metallic cation (calcium). These compositions ion optionally be administered with an adjuvant (col. 5

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lines 59+). Such compositions employing CT as adjuvant are shown in Tables 2 and 5-6. From the above teachings, instant claims 1-3, 10, 34 and 37 are clearly anticipated. Note that "comprising" language of instant claims any opens their scope to include any additional components taught by Bowersock et al.

Regarding dependent claims 11-12, Bowersock et al teach particle diameters of 1 to 100 microns (col. 5, lines 1+). This overlaps applicant's range of 50 to 250 microns.

For instant claim 35, note col. 5, lines 56+.

Regarding instant claim 38, Bowersock et al teach that their microparticles become preferentially absorbed (depotized) in Peyer's patches upon oral administration. See col. 5, lines 1-12 and Example 2.

Claims 1-4, 10, 34 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Bowersock et al (6,656,470).

Bowersock et al ('470), like Bowersock et al ('495) cited supra, teach immunogenic compositions containing cross-linked alginate microparticles and an adjuvant. They particularly teach use of mucosal adjuvant (col. 11, lines 13+). Bowersock et al ('470) teach that their alginate microparticles are cross-linked with a combination of two metallic cations listed at col. 3, lines 16+ and col. 24, lines 1+. These include metal ions recited in instant claim 4. From the above it is clear that instant claims 1-4, 10, 34 and 37 are anticipated.

Claims 1-4, 10-12, 34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombotz et al (5,900,238).

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Gombotz et al teach immunogenic compositions containing cross-linked alginate microparticles and, optionally, an adjuvant (col. 9, line 65-col. 10, line 8). The cross-linking cation can be strontium (col. 2, lines 65-67; col. 7, lines 65-67). As such instant claims 1-4, 10, 34 and 37 are clearly anticipated.

Regarding instant claims 11-12, the diameter range of 0.5-100 microns (col. 8, lines 46-48) is consistent with the 50-250 micron range instantly recited.

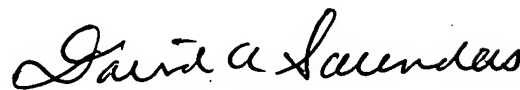
Claims 1 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz et al in view of Vogel et al.

Gombotz et al have been cited supra against claim 1. Since they point (col. 9, lines 4-8) merely to a compendium of vaccine adjuvants known in the art (Vogel et al.), it is taken that any of the art standard adjuvant of instant claims 7-8 would have been combined with the alginate microparticles of Gombotz et al. See Vogel et al at page 162 for CFA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-0507.

Saunders/LR
February 19, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644